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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,741	12/10/2003	Thomas M. Schmitt	2223-171	5362

1059 7590 11/30/2004

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EXAMINER

LIETO, LOUIS D

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/731,741

Applicant(s)

SCHMITT ET AL.

Examiner

Louis D Lieto

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1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, 24, drawn to an *in vitro* system comprising a notch ligand that supports T cell lymphopoiesis, and a method of forming cells of the T cell lineage, classified in class 435, subclass 325.
- II. Claim 21, drawn to a composition that comprises a nutrient medium, classified in class 435, subclass 405.
- III. Claims 18-20, 22, 23, 25, and 26, drawn to a T cell lineage composition and a method for using a T cell lineage composition *in vitro*, classified in class 435, subclass 7.1.
- IV. Claims 18-20, 22, 23, 25, 27, and 28, drawn to a T cell lineage composition and a method for using a T cell lineage composition *in vivo*, classified in class 435, subclass 41.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, III, IV and II are patentably distinct. In the instant case the different inventions of group I is to an *in vitro* system comprising a notch ligand that supports T cell lymphopoiesis, and a method of forming cells of the T cell lineage, the invention of group III is to a T cell composition and an *in vitro* method of use, the invention of group IV is to a T cell composition and an *in vivo* method of use, while the invention of group II is to a composition that comprises a nutrient medium. . The inventions of groups I, III and IV do not require the

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culture medium of group II. Culture mediums that support T cell lymphopoiesis are well known in the art, such as those that include IL-2 and IL-15. Further, this medium is not required for a method of using a T cell composition since the T cells have already differentiated at the time of use.

Inventions I, III and IV are patentably distinct. In the instant case the different inventions of group I is to an *in vitro* system comprising a notch ligand that supports T cell lymphopoiesis, and a method of forming cells of the T cell lineage, while the invention of group III is to a T cell composition and an *in vitro* method of use, and the invention of group IV is to a T cell composition and an *in vivo* method of use. The T cell compositions of groups III and IV can be made by methods other than the system of group I, such as the fetal thymus organ culture system. Further, the system of group I has materially different requirements from the T cell compositions of groups III and IV, such as the presence of notch ligand and progenitor cells.

Inventions III and IV are patentably distinct. In the instant case the different inventions of group III is to a T cell composition and an *in vitro* method of use, while the invention of group IV is to a T cell composition and an *in vivo* method of use. The *in vitro* method of use of group III is to a method of screening modulators of the T cell lineage, which is a substantially different function than the *in vivo* method of treating disease of group IV. The *in vitro* method of use of group III involves different components, such as cell modulators, and methods of use, such as *in vitro* culture chambers versus *in vivo* routes of injection.

Furthermore, searching the inventions of groups I-IV together would impose a serious search burden. In the instant case, the search of a composition comprising a culture medium is unrelated to an *in vitro* system comprising a notch ligand that supports T cell lymphopoiesis, and

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a method of forming cells of the T cell lineage. a T cell composition, and *in vitro* or *in vivo* methods of using a T cell composition. The method of group I encompasses substantially different areas of the art than group III and IV, such as progenitor cells and lineage differentiation conditions. Likewise, the search of a method of using a T cell lineage encompasses, methods of transplant, screening mechanisms and identification of disease suitable for treatment. Further, the composition of group II encompasses a wide variety of potential components not required for the inventions of groups I, III and IV. Thus, the search for groups I-III is not co-extensive. Finally, the inventions of Groups I -III have a separate status in the art as shown by their different sub-classifications. As such, it would be burdensome to search the inventions of groups I-III together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy J Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with,

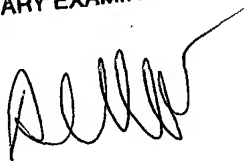
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Dr. Louis D. Lieto  
Patent Examiner  
Art Unit 1632

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbe', is written below the printed name and title.